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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,207	01/21/2004	Mark Nadel	C0989.70037US00	2512
7590 Walt Norfleet Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210			EXAMINER SIMS, JASON M	
			ART UNIT 1631	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/762,207	Applicant(s) NADEL ET AL.	
	Examiner Jason M. Sims	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 66-134 is/are pending in the application.
- 4a) Of the above claim(s) 69,70,74-87 and 100-133 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66-68,71-73,88-99 and 134 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/02/2005 and 7/1/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of group I, claims 66-99 and 134, and the election of the species of claims 67, 72, and 73 in the reply filed on 11/2/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 69,70,74-87 and 100-133 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventive group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/2/06.

Claims 66-68, 71-73, 88-99, and 134 are the current claims hereby under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 66-68, 71-73, 88-99, and 134 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 66 and 134, involve a method step of calculating proportions of a first and a second emission signal, which is vague and indefinite. It is unclear as to how "proportions" are calculated and with what the values are in reference to, which are involved in the calculation. Clearer claim wording is required.

Claims 66 and 134 contain the wording "on a side of the timing event," which has been deemed as vague and indefinite as to what it refers. Clearer claim wording is required.

Claims 67-68 contain the wording "a first portion," whereby the word "portion" is vague and indefinite as to its metes and bounds or what accounts for a "portion" of the signal. Clearer claim wording is required.

Claim 98 recites the limitation "the reset time" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 99 recites the limitation "the detection distance" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 71-73 and 88-97 are rejected as being dependent on rejected claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 66-68, 71-73, 88-99, and 134 are drawn to a process. A statutory process must include a final resulting step of a physical transformation, or produce a useful, concrete, and tangible result (*State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998), *AT&T Corp. v. Excel Communications Inc.* (CAFC 50 USPQ2d 1447 (1999))). The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

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As noted in *State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to 9-- process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. See *In re Warmerdam*, 33 F.3d 1354, 1359, 31 USPQ2d 1754, 1757-58 (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 66-68, 71-73, 88-99, and 134 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that

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a result of the method is outputted to a display or a memory or another computer on a network, or to a user, or by including a final resulting step of a physical transformation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 66-68, 71-73, 88-99, and 134 are rejected under 35 U.S.C. 102(e) as being anticipated by Chan (P/N 6,355,420).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The claims are directed to a method of analyzing polymers through high resolution linear analysis. The polymer has a first and second specific markers with first and second specific labels at a separation distance; a detection zone is provided where a timing event is established and the polymer is moved through the detection zone at a velocity, whereby the first and second emissions by the first and second

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labels are detected and proportions of the first and second emissions are calculated and compared to determine the separation distance of the first and second markers.

Chan teaches claims 66, 88-97, and 134 at col. 7 - col. 10. Chan at col. 7 and 8 discusses the analysis of polymers by analyzing a polymer as it is moving through a nanochannel. Chan discusses at col. 8, lines 40-48, that the analysis may involve a measurement of the time elapsed between detected signals, which indicates the distance between two units or the length of the polymer. Chan further discusses at col. 8, lines 58-62, at least two units of the polymer are labeled differently so as to produce two different detectable signals. Chan discusses at col. 10, lines 57-64, that the polymers may be any type of polymer known in the art, such as a nucleic acid or proteins and that different labels can be used to label different linked units to produce different signals, such as a fluorophore or an electromagnetic label.

Claims 66-68, 71-73, 88-99, and 134 are rejected under 35 U.S.C. 102(e) as being anticipated by Gilmanishin et al. (P/N 6,263,286).

Gilmanishin et al. teaches claim 66-68, 71-73, 88-99, and 134 at the abstract, col. 5, lines 50-62, col. 14, lines 33-48, and col. 15, lines 30-67. Gilmanishin et al., in the abstract, discusses determining the spatial separation of specific sites within a polymer. Gilmanishin et al. in the background discusses how polymers can be biological macromolecules such as DNA. Gilmanishin et al. at col. 5, lines 50-62, discusses using a polymer, or extended object, that is similarly labeled with at least two unit-specific markers and passes through a station where the impulses, or signals, are measured

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and an autocorrelation function is calculated, which reads on a timing event and analyzes the polymer by determining the separation distance between the measured impulses or signals. Gilmanishin et al. at col. 14, lines 33-48, discusses the calculation of the separation distance between the two unit-specific markers. Gilmanishin et al. at col. 15, lines 30-67, discusses what the different polymers and what the different labels may be.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would be obvious over, the reference claim(s). see, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 66 and 134 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of patent number 6,263,286. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are a species of the patented claims.

Claim Rejections - 35 USC § 102(f)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

Claims 66-68, 71-73, 88-99, and 134 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

For the reasons discussed above, it is apparent that Gilmanshin et al. (P/N 6,263,286) contains claimed subject matter in claims that is not patentably distinct from instant claims 66 and 134. Because the inventive entity of Gilmanshin et al. (P/N 6,263,286) is different from the instant application, a rejection is appropriate under 35 U.S.C. 102(f). This rejection could be overcome by amendment of the appropriate claims so that the claims are patentably distinct, or by filing a declaration stating the inventive entity for the commonly claimed subject matter is identical.

Conclusion

No Claim is allowed

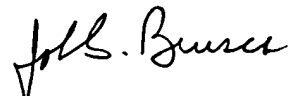
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Irem Yucel can be reached via telephone (571)-272-0781.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //


JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER